

## Food and Drug Administration, HHS

## § 177.1810

$\alpha,\alpha',\alpha''$ -[Propylidynetris (methylene)] tris [ $\omega$ -hydroxypoly (oxypropylene) (minimum 1.5 moles)], minimum molecular weight 400.  
 $\alpha$ -[p(1,1,3,3-Tetramethylbutyl) - phenyl]- $\omega$ -hydroxypoly(oxyethylene) (5 moles), average molecular weight 425.  
 Trimethylol propane.

(b) Optional adjuvant substances employed in the production of the polyurethane resins or added thereto to impart desired technical or physical properties may include the following substances:

List of substances	Limitations
1-[(2-Aminoethyl)amino]2-propanol .....	As a curing agent.
1-(3-Chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride .....	As a preservative.
Colorants used in accordance with § 178.3297 of this chapter. .	
Dibutyltin diacetate .....	As a catalyst.
Dibutyltin dichloride .....	Do.
Dibutyltin dilaurate .....	Do.
<i>N,N</i> -Dimethyldodecylamine .....	Do.
<i>N</i> -Dodecylmorpholine .....	Do.
<i>a,a'</i> -[Isopropylidenebis( <i>p</i> -phenyleneoxy(2-hydroxytrimethylene) )bis( $\omega$ -hydroxypoly-(oxyethylene) (136–170 moles)], average molecular weight 15,000.	As a stabilizer.
4,4'-Methylenedianiline .....	As a curing agent.
1,1',1''-Nitrilotri-2-propanol .....	Do.
2,2'-( <i>p</i> -Phenylenedioxy) diethanol .....	Do.
Polyvinyl isobutyl ether .	
Polyvinyl methyl ether .	
Soyaalkyd resin .....	Conforming in composition with § 175.300 of this chapter and containing litharge not to exceed that residual from its use as the reaction catalyst and creosol not to exceed that required as an antioxidant.
Tetrakis [methylene-(2,5-di- <i>tert</i> -butyl-4-hydroxyhydrocinna- mate)]methane (CAS Reg. No. 6683–19–8) .	Stabilizer.
<i>N,N,N'</i> -Tetrakis (2-hydroxypropyl)ethylenediamine .....	As a curing agent.
Triethanolamine .....	Do.
Trimethyleneglycol di ( <i>p</i> -aminobenzoate) (CAS Reg. No. 57609–64–0) .	As a curing agent.

(c) An appropriate sample of the finished resin in the form in which it contacts food, when subjected to ASTM method D968–81, “Standard Test Methods for Abrasion Resistance of Organic Coatings by the Falling Abrasive Tester,” which is incorporated by reference (copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408), using No. 50 Emery abrasive in lieu of Ottawa sand, shall exhibit an abrasion coefficient of not less than 20 liters per mil of film thickness.

[42 FR 14572, Mar. 15, 1977, as amended at 46 FR 57033, Nov. 20, 1981; 49 FR 10110, Mar. 19, 1984; 50 FR 51847, Dec. 20, 1985; 56 FR 15278, Apr. 16, 1991; 56 FR 42933, Aug. 30, 1991]

### § 177.1810 Styrene block polymers.

The styrene block polymers identified in paragraph (a) of this section may be safely used as abrasives or as

components of articles intended for use in contact with food, subject to provisions of this section.

(a) For the purpose of this section, styrene block polymers are basic polymers manufactured as described in this paragraph, so that the finished polymers meet the specifications prescribed in paragraph (b) of this section, when tested by the methods described in paragraph (c) of this section.

(1) Styrene block polymers with 1,3-butadiene are those produced by the catalytic solution polymerization of styrene and 1,3-butadiene.

(2) Styrene block polymers with 2-methyl-1,3-butadiene are those produced by the catalytic solution polymerization of styrene and 2-methyl-1,3-butadiene.

(3) Styrene block polymers with 1,3-butadiene, hydrogenated are those produced by the catalytic solution polymerization of styrene and 1,3-butadiene, and subsequently hydrogenated.

(b) *Specifications:*

Styrene block polymers	Molecular weight (minimum)	Solubility	Glass transition points	Maximum extractable fraction in distilled water at specified temperatures, times, and thicknesses	Maximum extractable fraction in 50 percent ethanol at specified temperatures, times, and thicknesses
1. (i) Styrene block polymers with 1,3-butadiene; for use as articles or as components of articles that contact food of Types I, II, IV–B, VI, VII–B, and VIII identified in table 1 in § 176.170(c) of this chapter under conditions of use D, E, F, and G described in table 2 in § 176.170(c) of this chapter.	29,000	Completely soluble in toluene.	–98 °C (–144 °F) to –71 °C (–96 °F) and 86 °C (187 °F) to 122 °C (252 °F).	0.0039 mg/cm <sup>2</sup> (0.025 mg/in <sup>2</sup> ) of surface at reflux temperature for 30 min on a 0.19 cm (0.075 in) thick sample.	0.002 mg/cm <sup>2</sup> (0.01 mg/in <sup>2</sup> ) of surface at 66 °C (150 °F) for 2 hr on a 0.19 cm (0.075 in) thick sample.
(ii) Styrene block polymers with 1,3-butadiene; for use as components of pressure-sensitive adhesives that contact food of Types I, II, IV–B, VI, VII–B, and VIII identified in table 1 in § 176.170(c) of this chapter under conditions of use C, D, E, F and G described in table 2 in § 176.170(c) of this chapter, provided the pressure-sensitive adhesives be applied only to closure tapes for sealing containers having a capacity of not less than 160 cc (5.5 fluid ounces) and that the area of the adhesive exposed to food shall not exceed 4.03 cm <sup>2</sup> (0.625 in <sup>2</sup> ). The pressure-sensitive adhesive may contain terpene resins as identified in § 175.125(b)(2) of this chapter.	29,000	.....do .....	.....do .....	.....do .....	Do.
2. Styrene block polymers with 2-methyl-1,3-butadiene; for use as articles or as components of articles that contact food of Types I, II, IV–B, VI, VII–B, and VIII identified in table 1 in § 176.170(c) of this chapter.	29,000	.....do .....	–65 °C (–85 °F) to –47 °C (–53 °F) and 86 °C (187 °F) to 122 °C (252 °F).	0.002 mg/cm <sup>2</sup> (0.01 mg/in <sup>2</sup> ) of surface at reflux temperature for 2 hr on a 0.071 cm (0.028 in) thick sample. (Optionally, maximum net residue soluble in chloroform shall not exceed 0.00020 mg/cm <sup>2</sup> (0.0013 mg/in <sup>2</sup> ) of surface.)	0.002 mg/cm <sup>2</sup> (0.01 mg/in <sup>2</sup> ) of surface at 66 °C (150 °F) for 2 hr on a 0.071 cm (0.028 in) thick sample. (Optionally, maximum net residue soluble in chloroform shall not exceed 0.00040 mg/cm <sup>2</sup> (0.0025 mg/in <sup>2</sup> ) of surface.)
3. (i) Styrene block polymers with 1,3-butadiene, hydrogenated (CAS Reg. No. 66070–58–4); for use as articles or as components of articles that contact food of Types I, II, IV–B, VI, VII–B, and VIII identified in table 1 in § 176.170(c) of this chapter.	16,000	.....do .....	–50 °C (–58 °F) to –30 °C (–22 °F) and 92 °C (198 °F) to 98 °C (208 °F).	0.002 mg/cm <sup>2</sup> (0.01 mg/in <sup>2</sup> ) of surface at reflux temperature for 2 hr on a 0.071 cm (0.028 in) thick sample.	0.002 mg/cm <sup>2</sup> (0.01 mg/in <sup>2</sup> ) of surface at 66 °C (150 °F) for 2 hr on a 0.071 cm (0.028 in) thick sample.
(ii) Styrene block polymers with 1,3-butadiene, hydrogenated (CAS Reg. No. 66070–58–4); for use at levels not to exceed 42.4 percent by weight as a component of closures with sealing gaskets that would contact food of Types III, IV–A, V, VII–A, VIII, and IX identified in table 1 in § 176.170(c) of this chapter, and in condition of use D as described under table 2 in § 176.170(c) of this chapter.	16,000	.....do .....	.....do .....	.....do .....	Do.

(c) The analytical methods for determining whether styrene block polymers conform to the specifications prescribed in this section are as follows and are applicable to the finished polymer.

(1) *Molecular weight.* Molecular weight shall be determined by intrinsic viscosity (or other suitable method).

(2) *Glass transition points.* The glass transition points shall be determined by either of the following methods:

(i) ASTM method D2236-70 ("Standard Method of Test for Dynamic Mechanical Properties of Plastics by Means of Torsional Pendulum," which is incorporated by reference; copies are available from American Society for Testing and Materials (ASTM), 1916 Race Street, Philadelphia, PA 19103, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408) modified by using a forced resonant vibration instead of a fixed vibration and by using frequencies of 25 to 40 cycles per second instead of 0.1 to 10 cycles per second.

(ii) Direct reading viscoelastometric method titled "Direct Reading Viscoelastometric Method for Determining Glass Transition Points of Styrene Block Polymers" (which is incorporated by reference; copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408), by which the glass transition points are determined in the tensile mode of deformation at a frequency of 35 hertz using a Rheovibron Model DDV-II (or equivalent) Direct Reading Viscoelastometer. Take maxima in the out-of-phase component of the complex modulus as the glass transition points. For block polymers of low styrene content or for simple block polymers, the polymer may be treated with 0.3 part per hundred dicumyl peroxide and

cured for 30 minutes at 153 °C to accentuate the upper transition point.

(3) *Maximum extractable fractions in distilled water and 50 percent ethanol and the maximum net residue solubles in chloroform.* The maximum extractable fractions in distilled water and 50 percent ethanol, and the maximum net residue solubles in chloroform, shall be determined in accordance with §176.170(d)(3) of this chapter using a sandwich form of the finished copolymer of the specified thickness and for the time and temperature specified in paragraph (b) of this section.

(d) The provisions of this section are not applicable to butadiene-styrene copolymers listed in other sections of this subpart.

(e) The provisions of this section are not applicable to styrene block polymers with 1,3-butadiene listed in §175.105 of this chapter.

[42 FR 14572, Mar. 15, 1977, as amended at 42 FR 43621, Aug. 30, 1977; 47 FR 11844, Mar. 19, 1982; 51 FR 16828, May 7, 1986; 54 FR 24898, June 12, 1989; 58 FR 65546, Dec. 15, 1993]

#### § 177.1820 Styrene-maleic anhydride copolymers.

Styrene-maleic anhydride copolymers identified in paragraph (a) of this section may be safely used as articles or components of articles intended for use in contact with food, subject to provisions of this section.

(a) For the purpose of this section, styrene-maleic anhydride copolymers are those produced by the polymerization of styrene and maleic anhydride so that the finished polymers meet the specifications prescribed in paragraph (b) of this section, when tested by the methods described in paragraph (c) of this section.

(b) *Specifications:*